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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/036,317	12/28/2001	Gregory M. Lanza	532512000312	4427

7590 09/11/2003

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EXAMINER

HARTLEY, MICHAEL G

ART UNIT	PAPER NUMBER
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1616

DATE MAILED: 09/11/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Applicati n No.

10/036,317

Applicant(s)

LANZA ET AL.

Examiner

Michael G. Hartley

Art Unit

1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 20-31 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 20-31 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

Response to Amendment

The preliminary amendments filed 12/28/2001 and 8/26/2003 have been entered. Consequently, claims 20-31 are pending and have been examined herein.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 20, 24 and 28 are rejected under 35 U.S.C. 102(e) as being anticipated by Unger (US 5,922,304).

Unger discloses a method of enhancing MRI comprising administering a contrast agent and detecting said contrast agent. The contrast agent comprises a ligand bound, lipid-coated liquid perfluorocarbon particle in an emulsion, see abstract and columns 4-5 column 4, lines 51+ and columns 29-30. The particles contain a liquid perfluorocarbon that is encapsulated in the microspheres, see column 5, lines 24-28 and column 8, lines 56+. The particles include a targeting agent (i.e., ligand), see column 9, lines 65+. The compositions may further comprise a therapeutic agent, see column 37, line 9.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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Claims 20-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Unger (US 5,922,304).

Unger '304 discloses a method of enhancing MRI comprising administering and detecting a contrast comprising a ligand bound, lipid-coated liquid perfluorocarbon particle in an emulsion, as set forth above. Unger also teaches that the particles contain a targeting agent and a therapeutic.

Unger '304 fails to specifically disclose the use of the same targeting agents (e.g., antibodies) and therapeutics (e.g., chemotherapeutics) as claimed.

Unger '112 teaches analogous compositions that are useful as MRI contrast agents, see abstract and column 4, lines 45+. Unger '112 teaches that antibodies may be bound to the particles to provide the advantage of targeting desired tissues *in vivo*, see column 25, lines 15+. Unger '112 also teaches that various therapeutic agents may be included in the compositions to provide for the desired therapeutic effect, including chemotherapeutics and genetic materials, see column 32, lines 14+.

It would have been obvious to one of ordinary skill in the art to include antibodies as a targeting agent in the particles disclosed by Unger '304 because it is well known in the art that antibodies may be bound to such MRI contrast agent particle compositions to provide the advantage of aiding the targeting of desired tissues, as shown by Unger '112. Also, it would have been obvious to one of ordinary skill in the art to include the therapeutic agents as claimed as the therapeutic agent disclosed by Unger '112 because such therapeutic agents are known to be useful in such compositions to provide a desired therapeutic effects, such as, for the treatment of cancer, etc., as shown by Unger '112. For example, Unger '112 teaches the advantage of including such therapeutic agents in MRI contrast agents to provide the advantage of imaging and/or treatment of tumors, and that the use of a targeting agent provides site specificity to the agent to improve *in vivo* localization.

Conclusion

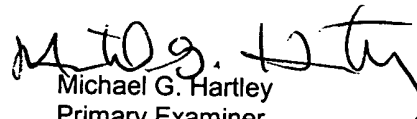
No claims are allowed at this time.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael G. Hartley whose telephone number is (703) 308-4411. The examiner can normally be reached on M-F, 7:30-5, off alternative Mondays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (703) 308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.


Michael G. Hartley
Primary Examiner
Art Unit 1616

MH